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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,643	12/22/2000	Todd M. Boyce	285-113 CON	1535

7590 04/19/2002
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/19/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,643

Applicant(s)

BOYCE ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Species VII in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 10-17,25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: On page 17, line 7, reference "37" for slot. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: reference character "32" has been used to designate both "slot," line 19 of page 13 and "bore," line 19 of page 17.

On page 19, lines 11 and 16 recite implant "10" and it should recite **100**.

On page 20, line 3 recites throughbore "34" and it should recite **134**.

Appropriate correction is required.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since the "at least two tabs" are "longitudinally spaced along thebody" as recited in claim 1 and include the first and second tabs as recited in claim 2, the positioning of the "first tab" with respect to the "second tab" is already understood to be "longitudinally spaced". This limitation appears to be ambiguous.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2, it is unclear from the wording whether or not one of "the at least two tabs" include **additional** *first and second tabs* extending radially outward *from each* of "the at least two tabs," meaning integral with.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-7,9 are rejected under 35 U.S.C. 102(b) as being anticipated by Godefroy et al. (5683463). Fig. 6 shows a "substantially" cylindrical body having at least two tabs **16**, **14** longitudinally displaced and are at least less or *equal* to the maximum diameter of the body. It can also be seen there is at least one throughbore **9**. Fig. 1 shows a body portion with one end having an installation slot **24** and a bore **23** between the slot.

Claims 1-5,8,9,18, 19, 21,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Marino (6290724). Marino shows (Fig. 1A) a "substantially" cylindrical body with at least two tabs **36** longitudinally placed from the two ends of the vertebral implant. The use of "substantially cylindrical body" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be seen that the tabs are radially spaced that a first tab is approximately 180° from a second tab on the opposite side. It can also be seen that

there is a throughbore 42 which is perpendicular to the longitudinal axis and radially spaced from the tabs. The tabs have a width less than or *equal* to the maximum diameter of the body. Marino discloses the implant is formed from a biocompatible material, such as human bone, col. 6, lines 31-42.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Scarborough (5676146). Marino is explained supra. However, Marino does not disclose the use of animal bone for the implant. Scarborough teaches to use animal bone for an implant, col. 2, lines 13-15 and for vertebral repair, col. 3, lines 11-22. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Scarborough in the implant of Marino in order to provide a radiolucent material for easier tracking the implant after implantation.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Lewandrowski et al. (J. Biomat. Res.). Marino is explained supra. However, Marino does not disclose the surface is demineralized. Lewandrowski et al. teach that demineralization enhances bone osteoinductive properties, p.365. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by

Lewandrowski et al. in the implant of Marino in order to provide a prosthesis capable of stabilizing the vertebrae while stimulate bone ingrowth.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Kuslich et al. (5445639). Marino is explained supra. Marino discloses forming a core and the implant is positioned by rotating, col. 14, lines 12-26. Marino also discloses implants and the vertebral space that the implant engages are often matched with respect to one another, col. 4, lines 10-24. However, Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae. Kuslich et al. teach to bore areas for vertebral implants with progressively increased blades that can be interpreted to be a stepped bore form, col. 7, lines 55-66. Fig. 17 shows an enlarged chamber or stepped bore. Kuslich also teaches the stepped bore can be used for dowels or tabs. It would have been obvious to one of ordinary skill in the art to use the method of boring vertebrae in a stepped fashion as taught by Kuslich et al. for inserting the implant of Marino in the implanting procedure in order to provide a ready-made chamber that would not require any forceful rotation or positioning.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4,6,18,19, 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,6,10,16,23 of copending Application No. 09/328283. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a central body with radially extending protrusions along the longitudinal axis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

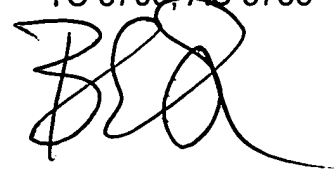
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
April 13, 2002

Bruce Snow
Primary Examiner
TC 3700, AU 3738

A handwritten signature in black ink, appearing to be 'BS', is written over the printed name and title of the Primary Examiner, Bruce Snow.